Notice of Allowability	Application No.	Applicant(s)	
	10/643,011	FAOUR ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *08 August 2005*.

2. ☒ The allowed claim(s) is/are *1-44*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawings filed 08/18/2003 are accepted by the Examiner.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *7/6/06* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Humera N. Sheikh
HUMERA N. SHEIKH
PATENT EXAMINER
TC- 1600

DETAILED ACTION

Status of the Application

Receipt of the Preliminary Amendment and Applicant's Arguments/Remarks, both filed 08/08/05, the request for extension of time (2 months-granted) filed 03/09/04 and the Terminal Disclaimer filed 07/07/06 is acknowledged.

Claims 1-44 are pending in this action. Claim 1 has been amended. Claims 1-44 are allowed.

Terminal Disclaimer

The terminal disclaimer filed on 07/06/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent No. 6,613,357 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rick Matos on July 06, 2006.

The application has been amended as follows:

In the Specification:

On page 1, line 23, after the term "Allegra-D™", the phrase "**(Hoechst Marion Roussel, Inc., Kansas City, Mo.)**" has been **added**.

On page 1, line 23, after the term "Claritin-D™", the phrase "**(Schering-Plough, Kenilworth, NJ)**" has been **added**.

On page 1, line 23, after the term "Claritin-D™ 24-Hour", the phrase "**(Schering-Plough, Kenilworth, NJ)**" has been **added**.

On page 1, line 23, after the term "Seldane-D™", the phrase "**(Hoechst Marion Roussel, Inc., Kansas City, Mo.)**" has been **added**.

On page 2, line 1, after the term "Semprex-D™", the phrase "**(Celltech, CA, Inc.)**" has been **added**.

On page 20, line 20, after the term "Eudragit™ L-30-D (MA-EA, 1:1)", the term "**(Rohm Pharma, Germany)**" has been **added**.

On page 20, lines 20-21, after the term "Eudragit™ L-100-55 (MA-EA, 1:1)", the term "**(Rohm Pharma, Germany)**" has been **added**.

On page 20, line 22, after the term "Coateric™ (PVAP)", the term "**(Colorcon, Ltd.)**" has been **added**.

On page 20, line 22, after the term "Aquateric™ (CAP)", the term "**(FMC Corporation)**" has been **added**.

On page 20, line 22, after the term "AQOAT™ (HPMCAS)", the term "**(Shin-Etsu Chemical Co., Ltd., Tokyo, Japan)**" has been **added**.

In the Claims:

In **claim 1**, line 12, the term "*H1 antagonist*" has been replaced with "**fexofenadine**".

In **claim 6**, line 1, the term "*H1 antagonist*" has been replaced with "**fexofenadine**".

In **claim 9**, line 1, the term "*H1 antagonist*" has been replaced with "**fexofenadine**".

In **claim 10**, line 1, the term "*H1 antagonist*" has been replaced with "**fexofenadine**".

In **claim 11**, line 1, the term "*H1 antagonist*" has been replaced with "**fexofenadine**".

Allowable Subject Matter

Claims 1-44 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art does not disclose nor teach the instant osmotic device comprising a combination of pseudoephedrine and fexofenadine having the instantly claimed release rate profiles. The prior art does not disclose or teach an osmotic device whereby at least 93±7% of pseudoephedrine released within 23 hours and at least 65% of fexofenadine is released within about 40 minutes after exposure of the osmotic device to an aqueous environment. The prior art also does not disclose or teach the instant osmotic device having a core of active ingredient that provides controlled release of drug (pseudoephedrine), a semipermeable membrane surrounding the core and an external erodible or water-soluble coating for rapid release of the H1 antagonist, fexofenadine as instantly claimed. The prior art fails to

disclose or teach an osmotic device having a drug-containing external coat that has been spray coated rather than compression coated onto the device.

The instant invention demonstrates an improvement over prior art formulations in that it provides for specific formulations, plasma or release profiles for obtaining various combinations of active ingredients. The instant osmotic device allows for the delivery of two different dosage forms from a single osmotic device. The instant device provides for once-daily administration with reduced side effects due to the reduced occurrence of interdose fluctuation of the plasma concentration of decongestant. The instant invention also provides for increased patient compliance.

Hence, in view of the improvements demonstrated by the instant invention, the instant invention is rendered patentable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

July 06, 2006

hns